Available online at www.sciencedirect.com
SCIENCE DIRECT®
ELSEVIER
International Journal of Food Microbiology xx (2006) xxx – xxx
INTERNATIONAL JOURNAL OF Food Microbiology
www.elsevier.com/locate/ijfoodmicro

Quantitative risk assessment of *Campylobacter* spp. in poultry based meat preparations as one of the factors to support the development of risk-based microbiological criteria in Belgium

M. Uyttendaele [a,*], K. Baert [a], Y. Ghafir [b], G. Daube [b], L. De Zutter [c], L. Herman [d], K. Dierick [e], D. Pierard [f], J.J. Dubois [g], B. Horion [h], J. Debevere [a]

[a] *Laboratory of Food Microbiology and Food Preservation, Faculty of Bioscience Engineering, Ghent University, Coupure links 653, B-9000 Ghent, Belgium*
[b] *Department of Food Sciences — Microbiology, Faculty of Veterinary Medicine, University of Liege, Liège, Belgium*
[c] *Department of Veterinary Public Health and Food Safety, Faculty of Veterinary Medicine, Ghent University, Ghent, Belgium*
[d] *Department of Animal Product Quality, Agricultural Research Centre, Ministry of the Flemish Community, Melle, Belgium*
[e] *Laboratory of Food Microbiology, Bacteriology Section, Institute of Public Health, Ministry of Public Health, Safety of the Food Chain and Environment, Brussels, Belgium*
[f] *Laboratory of Microbiology, Academic Hospital of the Vrije Universiteit Brussel, Brussels, Belgium*
[g] *Belgian Health Council, Brussels, Belgium*
[h] *Federal Public Service (FPS) Health, Food Chain Safety and Environment, Brussels, Belgium*

Received 28 September 2005; received in revised form 6 March 2006; accepted 12 May 2006

Abstract

The objective of this study was to do an exercise in risk assessment on *Campylobacter* spp. for poultry based meat preparations in Belgium. This risk assessment was undertaken on the demand of the competent national authorities as one of the supportive factors to define risk-based microbiological criteria. The quantitative risk assessment model follows a retail to table approach and is divided in different modules. The contamination of raw chicken meat products (CMPs) was represented by a normal distribution of the natural logarithm of the concentration of *Campylobacter* spp. (ln[Camp]) in raw CMPs based on data from surveillance programs in Belgium. To analyse the relative impact of reducing the risk of campylobacteriosis associated with a decrease in the *Campylobacter* contamination level in these types of food products, the model was run for different means and standard deviations of the normal distribution of the ln[Camp] in raw CMPs. The limitation in data for the local situation in Belgium and on this particular product and more precisely the semi-quantitative nature of concentration of *Campylobacter* spp. due to presence/absence testing, was identified as an important information gap. Also the knowledge on the dose–response relationship of *Campylobacter* spp. was limited, and therefore three different approaches of dose–response modelling were compared. Two approaches (1 and 2), derived from the same study, showed that the reduction of the mean of the distribution representing the ln[Camp] in raw CMPs is the best approach to reduce the risk of *Campylobacter* spp. in CMPs. However, for the simulated exposure and approach 3 it was observed that the reduction of the standard deviation is the most appropriate technique to lower the risk of campylobacteriosis. Since the dose–response models used in approach 1 and 2 are based on limited data and the reduction of the mean corresponds with a complete shift of the contamination level of raw CMPs, demanding high efforts from the poultry industry, it is proposed to lower the standard deviation of the concentration of *Campylobacter* spp. in raw CMPs. This proposal corresponds with the elimination of the products that are highly contaminated. Simulation showed that eating raw chicken meat products can give rise to exposures that are 10^{10} times higher than when the product is heated, indicating that campaigns are important to inform consumers about the necessity of an appropriate heat treatment of these type of food products.

Keywords: *Campylobacter*; Quantitative risk assessment; Poultry based meat preparations; Microbiological limit

* Corresponding author. Tel.: +32 9 264 61 78; fax: +32 9 255 55 10.
E-mail address: mieke.uyttendaele@UGent.be (M. Uyttendaele).

0168-1605/$ - see front matter © 2006 Elsevier B.V. All rights reserved.
doi:10.1016/j.ijfoodmicro.2006.05.023

1. Introduction

Campylobacter spp. are a common cause of bacterial gastroenteritis in humans. Poultry handling and consumption are considered to be risk factors in acquiring campylobacteriosis (Kapperud et al., 1993; NACMF, 1994; Cahill, 2004). Since 1997, the Belgian zoonoses surveillance program has assessed the national contamination with *Campylobacter* spp. of chicken carcasses and fillets by taking samples from slaughterhouses, meat processing plants and retailers. The *Campylobacter* spp. contamination of poultry has remained at the same level since 2000, i.e. 18% on fillet samples (sample size 1 g) and 35% on carcasses (sample size 0.01 g). Broiler carcasses and fillets sampled at retail level were significantly less contaminated than samples from production plants (Ghafir et al., submitted for publication). In 2002, as a part of the Belgian monitoring program on the presence of pathogenic bacteria in poultry based meat preparations such as poultry sausages and poultry hamburger at the retail level, *Campylobacter* spp. was found to be present in 94 out of 289 samples (32.5%) (analysis per 25 g) and limited subsampling showed 4 out of 15 samples to be positive for *Campylobacter* spp. per 0.01 g (Anonymous, 2003; Ghafir et al., submitted for publication). Since poultry based meat preparations are susceptible to mishandling during preparation by the consumer and *Campylobacter* spp. are frequently isolated and occasionally at high contamination level (more than 100/g), there was an enhanced need by the competent food authorities to define risk-based microbiological criteria for the pathogen in this type of food product.

The mere finding, with a presence–absence test, of certain organisms known to cause foodborne illness (e.g. *Campylobacter* spp.) does not necessarily indicate a threat to public health. However, neither in the national nor in European legislations are criteria on the acceptable *Campylobacter* contamination level in these types of foods available. The determination of a "maximum acceptable level" for *Campylobacter* spp. in poultry based meat preparations could be used to develop food safety measures throughout the food chain and as such improve the microbiological quality of these type of products and subsequently improve public health. These food safety measures may include the development of a microbiological limit.

According to the Codex principles, the European Commission strategy for establishment and setting microbiological criteria in foodstuffs, and the European regulation EC No. 178/2002, that demand that food law is based on risk analysis (European Parliament and Council, 2002), the Federal Public Service (FPS) Health, Food Chain Safety and Environment formulated a demand to the Belgian Health Council at the end of November 2003 to start, taking into account the limitations in time and manpower available, an exercise in risk assessment on *Campylobacter* spp. specifically for poultry based meat preparations in Belgium. The objective was to use this exercise in scientific risk assessment as one of the supportive factors to define risk-based microbiological criteria. More specifically the demand stipulated the relative relation on levels of *Campylobacter* spp. present at retail in these types of foods (e.g. absence per 25 g, per 10 g, per 1 g, per 0.1 g, per 0.01 g, etc.) and the threat it represents for public health. This manuscript includes a report of this exercise in risk assessment taking into account, if available, data from the Belgian situation together with information to be found in international literature and risk assessment projects on *Campylobacter* spp. in several industrialized countries (Rosenquist et al., 2003; Bogaardt et al., 2004) as well as at the international level by FAO/WHO (2002).

2. Materials and methods

2.1. Definition of the scope (pathogen/food type)

The pathogen *Campylobacter* spp. refers to the thermotolerant human pathogenic *Campylobacter* species: *Campylobacter jejuni*, *C. coli*, *C. lari* and *C. upsaliensis*. In the type of food product included in the study (poultry based meat preparations) the term *Campylobacter* spp. refers especially to *C. jejuni* and *C. coli*. The foodstuff is defined as poultry based meat preparations. Definition of a "meat preparation" refers to portioned, cut or minced meat to which spices or other ingredients to improve sensoric properties or texture might have also been added. Sausages and hamburgers of raw minced poultry meat were included as this type of food product. Apart from the minced poultry meat preparations, this product group also includes for example satés of chicken meat (pieces of poulry meat mounted on a wooden stick separated by onion or pepper slices) or marinated and spiced chicken wings, etc. It was accepted that all poultry based meat preparations are intended to undergo a heat treatment before consumption, but also the possibility for cross-contamination was taken into account.

2.2. Data collection on the issue of Campylobacter in poultry based meat preparations in Belgium and rationale for the QRAM

Data on the prevalence of *Campylobacter* spp. in poultry based meat preparations were derived from the National Belgian surveillance of zoonotic agents to comply with the

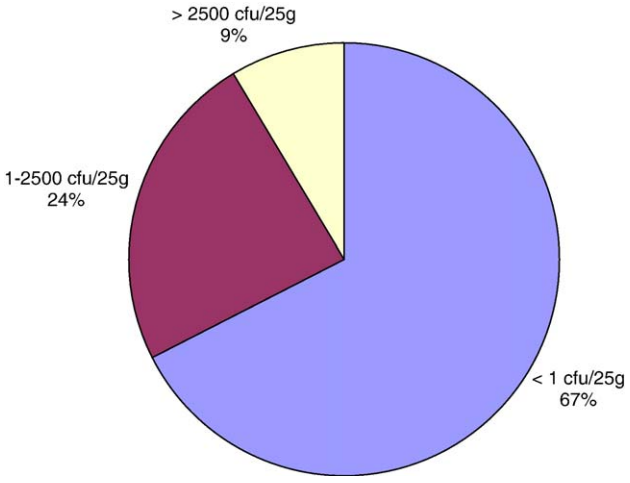


Fig. 1. Semi-quantitative distribution of the prevalence of *Campylobacter* in raw minced poultry preparations.

Directive 92/117/CEE (European Council, 1992). The detection consisted of a selective enrichment in Preston broth at 42 °C for 48 h, followed by the isolation on mCCDA at 42 °C for 24 h–120 h. Confirmation of minimum one colony was by miniaturised biochemical tests (API Campy, Biomérieux, France) and by PCR typing. The samples are taken by specifically trained inspectors from the Federal Agency for the Security of the Food Chain from establishments representative of the Belgian meat production and representative retail outlets in Belgium. From the accumulated data Fig. 1 could be distillated representing an indication of the level of contamination of *Campylobacter* spp. in poultry based meat preparations.

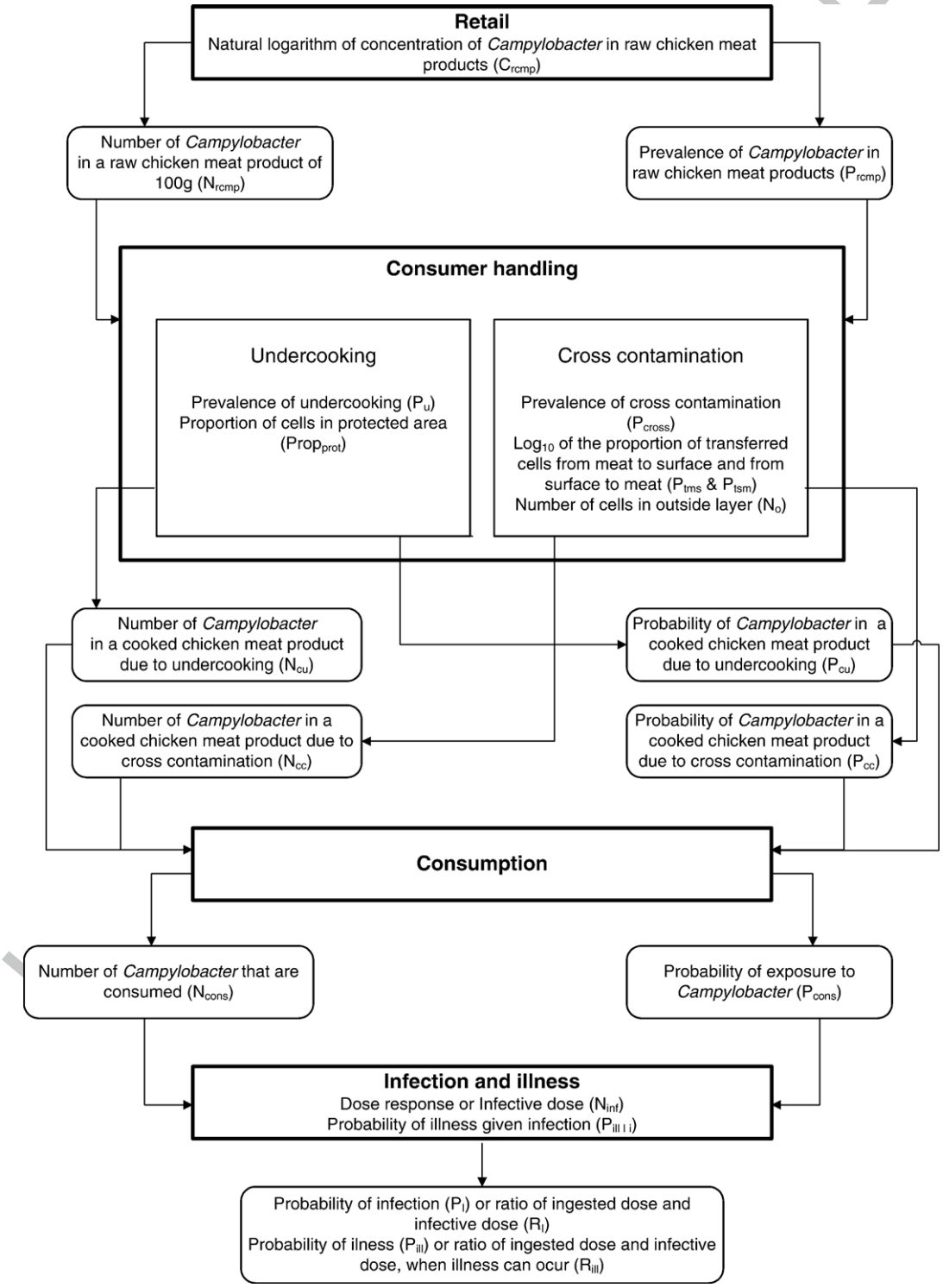


Fig. 2. Overview of the quantitative risk assessment model.

Table 1
Detailed overview of the quantitative risk assessment model and its assumptions

Module	Variable	Description	Unit	Distribution/model	Assumptions and references
Retail	C_{rcmp}	Natural logarithm of concentration of *Campylobacter* in raw chicken meat preparations	ln cfu/g	RiskNormal (μ;σ)	The level of *Campylobacter* spp. in raw chicken meat preparations is log normally distributed
	N_{rcmp}	Number of *Campylobacter* in a raw chicken meat preparation of 100g	cfu/ 100 g	exp(C_{rcmp})×100	
	P_{rcmp}	Prevalence of *Campylobacter* in raw chicken meat preparations	–	Fixed value depending on the distribution of C_{rcmp}	$P_{rcmp}=(A+0.1\times B+0.01\times C)/100$ A=percentage that contains 1 or more cfu per 100 g B=percentage of CMP that contains between 1 cfu/100 g and 1 cfu/1000 g C=percentage of CMP that contains between 1 cfu/1000 g and 1 cfu/10 000 g The percentage of contaminated CMP that contains less than 1 cfu/10 000 g was neglected
Consumer handling: undercooking	P_u	Prevalence of undercooking	–	RiskBeta(17;93)	16 out of 108 persons undercook (Worsfold and Griffith, 1997) = > beta (16+1, 108−16+1)
	O_u	Occurrence of undercooking: 0 = no undercooking, 1 = undercooking	–	RiskBinomial (1;P_u)	When this binomial generates a 0, no undercooking occurs, whereas 1 represents that the product is undercooked
	$Prop_{prot}$	Proportion of cells in protected area	–	Risktriang (0.1;0.15;0.2)	10 to 20% of the volume is protected against the heat transfer with a mode of 15% (FAO/WHO, 2002)
	N_{prot}	Number of *Campylobacter* that are protected	cfu/ 100 g	$N_{rcmp}\times Prop_{prot}$	
	N_u	Number of *Campylobacter* that survive undercooking	cfu/ 100 g	$N_{prot}\times 10\%$	If undercooking → core temperature 60–65 °C (FAO/WHO, 2002) and D 60 °C Camp.=1 min (ICMSF, 1996) → 1 log reduction (10% survival)
	N_{cu}	Number of *Campylobacter* in a cooked chicken meat preparation due to undercooking	cfu/ 100 g	If(O_u=0;0;N_u)	When the binomial distribution (for O_u) shows that no undercooking occurs, the number of *Campylobacter* spp. in a cooked chicken meat preparation will be 0. However, when undercooking occurs, N_{cu} will be equal to N_u.
	P_{cu}	Probability of *Campylobacter* in a chicken meat preparation due to undercooking	–	$P_{rcmp}\times P_u$	
Consumer handling: cross-contamination	P_{cross}	Prevalence of cross-contamination	–	RiskPert (0.25;0.5;0.76)	The results of different studies (Worsfold and Griffith, 1997; Williamson et al., 1992; Daniels, 1998) on consumer behaviour integrated in a Pert distribution
	O_{cross}	Occurrence of cross-contamination 0 = no cross-contamination 1 = cross-contamination	–	RiskBinomial (1;P_{cross})	When this binomial distribution generates a 0, no cross-contamination occurs, whereas 1 indicates that cross-contamination occurred.
	$Prop_{tms}$	Log_{10} of the Proportion of transferred cells from meat to surface	–	RiskPert (−6;−2;−1)	The log_{10} of the proportion of transferred cells from a meat product to a surface was represented by a Pert distribution with a minimum of −6, a mode of −2 and a maximum of −1 (FAO/WHO, 2002)
	N_o	Number of cells in outside layer	cfu/ 100 g	$N_{rcmp}\times 0.15$	The campylobacters in the 15 g outer contact side of a CMP can give rise to transmission. This assumption is based on calculations of the outer contact side. A homogenous distribution of the cells is assumed
	N_{tms}	Number of cells that are transferred from meat to surface	cfu/ 100 g	$N_o\times$ power (10,$Prop_{tms}$)	
	$Prop_{tsm}$	Log_{10} of the proportion of transferred cells from surface to meat	–	RiskPert (−6;−2;−1)	The log_{10} of the proportion of transferred cells from a meat product to a surface was represented by a Pert distribution with a minimum of −6, a mode of −2 and a maximum of −1 (FAO/WHO, 2002)
	N_{tsm}	Number of cells that are transferred from surface to meat	cfu/ 100 g	$N_{tms}\times$ power (10,$Prop_{tsm}$)	
	N_{cc}	Number of *Campylobacter* in a	cfu/	If(O_{cross}=0;0;N_{tsm})	When the binomial distribution (for O_{cross}) shows

Table 1 (*continued*)

Module	Variable	Description	Unit	Distribution/model	Assumptions and references
Consumer handling: cross-contamination					
		cooked chicken meat preparation due to cross-contamination	100 g		that no cross-contamination occurs, the number of *Campylobacter* spp. in a cooked chicken meat preparation will be 0. However, when cross-contamination occurs, N_{cc} will be equal to N_{tsm}
	P_{cc}	Probability of *Campylobacter* in a cooked chicken meat preparation due to cross-contamination	–	$P_{rcmp} \times P_{cross}$	
Consumption	N_{cons}	Number of *Campylobacter* that are consumed	CFU/100g	$N_{cu}+N_{cc}$	Each consumer eats a portion of 100 g
	P_{cons}	Probability of exposure	–	$P_{cu}+P_{cc}-P_{cu}\times P_{cc}$	Exposure is due to combination of cross-contamination and undercooking
Infection and illness 1	$P_I(D)$	Probability of infection of dose	–	$1-(1+N_{cons}/59.95)^{-0.21}$	Beta-poisson model to estimate the average risk to a population (FAO/WHO, 2002)
	P_I	Probability of infection	–	$P_{cons}\times P_I(D)$	
	$P_{ill\ 1\ i}$	Probability of illness given infection	–	RiskBeta(30;61)	29 individuals got sick out of 89 that were infected (Black et al., 1988) = > beta (29+1, 89−29+1)
	P_{ill}	Probability of illness		$P_I\times P_{ill\ 1\ i}$	
Infection and illness 2	$P_I(1)$	Probability of infection of 1 cell	–	RiskBeta (0.21;59.95)	Beta distribution with $\alpha=0.21$ and $\beta=59.95$ (FAO/WHO, 2002)
	$P_I(D)$	Probability of infection of dose	–	$1-(1-P_I(1))^{Ncons}$	Beta-poisson model for an individual (FAO/WHO, 2002)
	P_I	Probability of infection	–	$P_{cons}\times P_I(D)$	
	$P_{ill\ 1\ i}$	Probability of illness given infection	–	RiskBeta(30;61)	29 individuals got sick out of 89 that were infected (Black et al., 1988) = > beta (29+1, 89−29+1)
	P_{ill}	Probability of illness	–	$P_I\times P_{ill\ 1\ i}$	
Infection and illness 3	N_{inf}	Infective dose	cfu	RiskPert(500; 800; 100 000 000)	Minimum infective dose was estimated to be 500 based on Robinson (1981). The most likely value was estimated to be 800 and the maximum was estimated to be 10^8 based on Black et al. (1988).
	R_I	Ratio of ingested dose and infective dose: >1: infection, <1: no infection	–	N_{cons}/N_{inf}	
	$P_{ill\ 1\ i}$	Probability of illness given infection	–	RiskBeta(30;61)	29 individuals got sick out of 89 that were infected (Black et al., 1988) = > beta (29+1, 89−29+1)
	$O_{ill\ 1\ i}$	Occurrence of illness given infection	–	RiskBinomial $(1;P_{ill\ 1\ i})$	
	R_{ill}	Ratio of ingested dose and infective dose, when illness can occur: >1: illness, <1: no illness	–	If$(O_{ill\ 1\ i}=1; R_I;0)$	

2.3. Description of the model

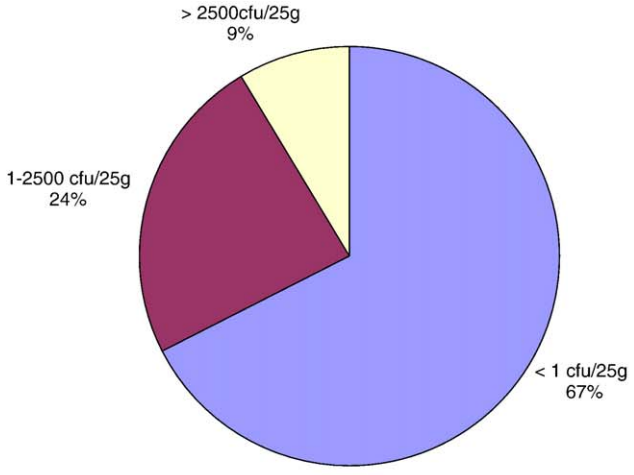
The QRAM follows a retail to table approach. The necessary data and scientific backup for assumptions in the QRAM were mainly derived from the risk assessment projects on *Campylobacter* spp. in the Netherlands (Bogaardt et al., 2004) and the international level (FAO/WHO, 2002) together with information to be found in national reports and international literature. It is established that the growth of *Campylobacter* spp. is only possible above 30 °C (NACMF, 1994) and *Campylobacter* spp. can survive well under cool (refrigeration temperature) and humid conditions (Yoon et al., 2004; Solow et al., 2003; Chan et al., 2003). Therefore, it was assumed in the QRAM that during storage of the (refrigerated) food product and occasional temperature abuse, that might reasonably be expected, no growth and (as a worst case scenario) also no reduction of the pathogen occurs.

The quantitative risk assessment model (QRAM) was constructed in an Excel Spreadsheet (Microsoft, USA) and was simulated using @RISK (Palisade, USA), an Excel add-in program. An overview of the QRAM is shown in Fig. 2. The QRAM is divided in different modules (Module 1 — Retail, Module 2 — Consumer handling (undercooking and cross-contamination), Module 3 — Consumption and Module 4 — Infection and illness). As shown in Fig. 2 the outputs of a module are used as inputs for the following module. The detailed model is given in Table 1. An overview of the assumptions made and references to reports or publications are also summarized in Table 1.

2.3.1. Module 1: retail

The first module describes the contamination level and prevalence of *Campylobacter* spp. in raw poultry based meat preparations that are available in the retail in Belgium.

Therefore, data from the Belgian national surveillance programs in 2002 (Anonymous, 2003; Ghafir et al., submitted for publication) on the prevalence of *Campylobacter* spp. in these poultry products were used as an input (Fig. 1). Since only presence/absence testing of *Campylobacter* spp. in 25 g (289 samples) and/or 0.01 g (15 samples) was performed, the available dataset was limited. It was assumed that the level of *Campylobacter* spp. in raw chicken meat preparations (CMP) was log normally distributed, since lognormal distributions are used for representing quantities that are thought of in orders of



Transformation of the data on the prevalence of Campylobacter in raw CMP in a cumulative distribution

Level of Campylobacter in raw CMP (CFU/g)	Cumulative probability
0.04	0.67
100	0.91
4000	1

Transformation of the data from CFU/g into ln CFU/g

C_{rcmp} (ln CFU/g)	Cumulative probability
-3.22	0.67
4.61	0.91
8.29	1

Fitting a normal distribution to the cumulative distribution consisting of 3 data points

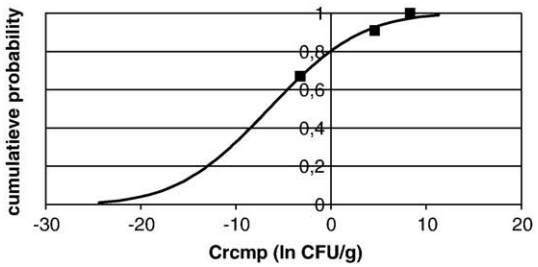


Fig. 3. Overview of the followed methodology to determine the mean and standard deviation of the natural logarithm of the concentration of *Campylobacter* in raw chicken meat preparations.

magnitude (Vose, 2000). However, when lognormal distributions are fitted to data, @RISK introduces a shift that reduces the understandability of the distributions. Therefore, the data expressed as cfu/g (colony forming units/gram) were transformed to ln cfu/g and a normal distribution was fitted. This data transformation can be done, since a variable is lognormally distributed when the natural logarithm of the variable is normally distributed, i.e. X is lognormally distributed if $\ln[X]$ is normally distributed (Vose, 2000). Fig. 3 shows the followed work methodology. Based on the fitted normal distribution the mean was −6.54 and the standard deviation was 7.67. This normal distribution of the natural logarithm of the concentration of *Campylobacter* spp. in raw chicken meat preparations (C_{rcmp}) was used to calculate the number of *Campylobacter* cells in a raw chicken meat preparation of 100 g (N_{rcmp}), 100 g being the assumed consumer portion. The prevalence of *Campylobacter* spp. in raw chicken meat preparations (P_{rcmp}) was manually determined from the distribution for C_{rcmp}. The percentage of chicken meat preparation was determined that has 1 or more cfu per 100 g, which corresponds with one or more cells per portion CMP. However, not only the CMP portions that contain 1 or more cfu per 100 g are definitely contaminated, also a certain percentage of the CMP that contain more than 1 cfu per 10 000 g but less than 1 cfu per 100 g should be included as contaminated portions. Therefore, the prevalence of contaminated CMP was calculated with Eq. (1).

$$P_{rcmp} = (A + 0.1 \times B + 0.01 \times C)/100 \quad (1)$$

with

A	percentage that contains 1 or more cfu per 100 g
B	percentage of CMP that contains between 1 cfu/100 g and 1 cfu/1000 g
C	percentage of CMP that contains between 1 cfu/1000 g and 1 cfu/10 000 g

The percentage of contaminated CMP that contains less than 1 cfu/10 000 g was neglected. The values for A, B and C can be derived from Table 3. This table gives the percentage of the population of CMP that exceeds different *Campylobacter* contamination levels (from 10^{-8} until 10^{6} cfu/g). Based on Table 3 it was calculated that the prevalence for the current situation (sit 1) was equal to $(40.05+0.1\times(51.91-40.05)+0.01\times(63.61-51.91))/100=41.35$.

2.3.2. Module 2: consumer handling

Studies have shown that the main factors responsible for outbreaks of food poisoning were inappropriate storage, inadequate cooking or reheating, and cross-contamination (Williamson et al., 1992; Worsfold and Griffith, 1997; Daniels, 1998). No data are available at present on food handling practices by the Belgian consumer, however a survey was set up and initiated in 2004 and is in progress at present in Belgium by the Belgian Federal Public Service (FPS) Health, Food Chain Safety and Environment to acquire information on the knowledge of basic rules of food hygiene. The present study has included two pathways in the model (i) cross-contamination of a meal due to unsafe food handling procedures, and (ii) the survival of *Campylobacter* spp. due to undercooking of the chicken.

2.3.2.1. Module 2a: consumer handling: undercooking. In this module the effect of cooking is taken into account. As *Campylobacter* is a heat sensitive micro-organism, proper heat treatment of a chicken meat preparation eliminates all campylobacters as an infectious agent from the portion. However, when the product is undercooked surviving campylobacters might cause illness. The prevalence of undercooking was determined by a beta distribution based on data of Worsfold and Griffith (1997). In order to determine whether undercooking occurs or not, a binomial distribution was used with 1 trial and a probability of success P_u. Although undercooking occurs, not all the cells will survive the heating process. Only the proportion of cells in the protected area will survive. This proportion was estimated by the FAO/WHO (2002). The number of *Campylobacter* spp. that is protected (N_{prot}) was then calculated as the multiplication of the number of *Campylobacter* spp. in a raw chicken meat preparation of 100 g (N_{rcmp}) and the proportion of cells that are present in protected areas ($Prop_{prot}$). However, when a product is heated to an outside temperature of 74 °C, a temperature of 60 to 65 °C is reached inside during 0.5 to 1.5 min (FAO/WHO, 2002). Since it has been reported (ICMSF, 1996) that the D-value of *Campylobacter* spp. at 60 °C is less than 1 min for poultry, one log reduction will still occur even in these protected areas. The number of *Campylobacter* spp. in a cooked chicken meat preparation due to undercooking (N_{cu}) is calculated using the occurrence of undercooking and the number of *Campylobacter* spp. that survive undercooking. The probability of *Campylobacter* spp. in a chicken meat preparation due to undercooking is equal to the multiplication of the prevalence of *Campylobacter* spp. in raw chicken meat preparations and the prevalence of undercooking.

2.3.2.2. Module 2b: consumer handling: cross-contamination. Besides undercooking, consumers can also cause cross-contamination. Estimating the occurrence of cross-contamination is a difficult task since the available quantitative and qualitative data are limited. A few studies have been performed in order to estimate consumer habits during food preparation, but no information was available for the Belgian situation. The prevalence of cross-contamination was described by a Pert distribution using data from different studies (Williamson et al., 1992; Worsfold and Griffith, 1997; Daniels, 1998). In order to determine whether cross-contamination occurs, a binomial distribution was used with 1 trial and a probability of success P_{cross}. When cross-contamination occurs for CMP, the cells are first transferred from the meat product to a surface (e.g. knife, cutting board) and those cells have to be transferred again from the surface to another food or the meat after cooking. However, not all cells are transferred. FAO/WHO (2002) modelled the variation of the fraction of *Campylobacter* spp. that is transferred from the raw chicken to preparation surfaces by a Pert distribution. However, not all the cells that are present in the meat

t2.1 Table 2
t2.2 Characteristics of the normal distributions of the natural logarithm of concentration of *Campylobacter* in raw chicken meat preparations

t2.3 Situation	1	2	3	4	5	6	7	8	9	10
t2.4 Mean	−6.54	−6.54	−6.54	−6.54	−6.54	−6.54	−6.54	−8.84	−8.84	−8.84
t2.5 Standard deviation	7.67	6.67	5.67	4.67	3.67	2.67	1.77	7.67	6.67	5.67

product are transferred, only the cells that are present in the outer layer can be transferred. Based on calculations of the outer contact side of a hamburger and a sausage, it was assumed that only campylobacters in the 15 g outer contact side of a 100 g CMP can give rise to transmission of the pathogen. In a subsequent step, the number of cells that are transferred from the meat to the surface is calculated by the multiplication of the number of cells in the outer layer and the fraction that is transferred. After cooking, a transfer will occur again from the surface to the meat product. This transfer is calculated in the same way as the transfer from the meat to the surface. The number of *Campylobacter* spp. in a cooked chicken meat preparation due to cross-contamination is then equal to 0 when no cross-contamination occurs, or is equal to the number of cells that are transferred from the surface to the meat when cross-contamination occurs. The probability of *Campylobacter* spp. in a cooked chicken meat preparation due to cross-contamination, equals the prevalence of *Campylobacter* spp. in raw chicken meat preparations multiplied by the prevalence of cross-contamination.

2.3.3. Module 3: consumption

Finally the chicken meat preparations will be consumed. It was assumed that each consumer eats a portion of 100 g. The number of campylobacters that are consumed is then equal to the sum of the number of *Campylobacter* spp. in a cooked chicken meat preparation (N_{cons}) due to undercooking and cross-contamination. The probability of exposure (P_{cons}) is calculated based on the probability of *Campylobacter* spp. in a cooked chicken meat preparation due to undercooking and cross-contamination.

2.3.4. Module 4: infection and illness

Only few studies describing the human response to a known dose of *Campylobacter* exist. In one experiment, a dose of 500 organisms ingested with milk caused illness in one volunteer (Robinson, 1981). In another experiment, doses ranging from 800 to 10^8 organisms caused diarrhoeal illness (Black et al., 1988). These few investigations indicate that the infective dose of *C. jejuni* may be relatively low. From the human feeding study a mathematical relation describing the risk of infection after exposure to *Campylobacter* spp. via food or water has been derived (Medema et al., 1996). In the QRAM three different approaches were used, since only limited data are available on the infective dose of *Campylobacter* spp. and as a consequence the reliability of the derived models is doubtable.

2.3.4.1. Module 4a: approach 1. In the first approach, the beta-poisson model that was developed by the Joint FAO/WHO Activities on Risk Assessment of Microbiological Hazards in Foods (FAO/WHO, 2002) was used (Table 1). This model is based on data from two strains of *C. jejuni*, in contrast to the model developed by Medema et al. (1996) and Teunis and Havelaar (2000), which were developed based on the data of one strain. The beta-poisson model was used to assess the probability of infection of the ingested dose. Since not every infected

t3.1 Table 3
t3.2 The percentage of the population with a concentration above a certain contamination level for the different tested situations

Campylobacter concentration (cfu/g)	Ln *Campylobacter* concentration (ln cfu/g)	Percentage of the population of raw chicken meat products above *Campylobacter* concentration									
		sit 1[a]	sit 2	sit 3	sit 4	sit 5	sit 6	sit 7	sit 8	sit 9	sit 10
1.0E–08	–18,42	93.93	96.26	98.19	99.45	99.94	100	100	89.42	92.45	95.44
1.0E–07	–16.12	89.42	92.45	95.44	97.99	99.55	99.98	100	82.87	86.25	90.04
1.0E–06	–13.82	82.87	86.25	90.04	94.05	97.64	99.68	100	74.19	77.24	81.01
1.0E–05	–11.51	74.15	77.19	80.96	85.64	91.22	96.87	99.75	63.61	65.55	68.11
1.0E–04	–9.21	63.61	65.55	68.11	71.662	76.65	84.13	93.43	51.92	52.21	52.6
1.0E–03	–6.91	51.90	52.21	52.6	53.16	54.02	55.51	58.28	40.06	38.62	36.68
1.0E–02	–4.61	40.05	38.61	36.68	33.97	29.95	23.49	13.78	29.06	26.3	22.78
1.0E–01	–2.30	29.01	26.25	22.73	18.2	12.4	5.61	0.83	19.69	16.34	12.44
1.0E+00	0.00	19.68	16.34	12.44	8.07	3.74	0.72	0.01	12.45	9.25	5.95
1.0E+01	2.30	12.44	9.25	5.95	2.92	0.8	0.05	0	7.31	4.74	2.47
1.0E+02	4.61	7.28	4.73	2.46	0.85	0.12	0	0	3.97	2.19	0.88
1.0E+03	6.91	5	2.19	0.88	0.2	0.01	0	0	2	0.91	0.27
1.0E+04	9.21	1.98	0.91	0.27	0.04	0	0	0	0.92	0.34	0.07
1.0E+05	11.51	0.91	0.34	0.07	0.01	0	0	0	0.39	0.11	0.02
1.0E+06	13.82	0.38	0.11	0.02	0	0	0	0	0.15	0.03	0
Microgiological limit[b] (cfu/g)		10^5	10^4	10^3	10^2	10^1	10^0	10^{-1}	10^4	10^3	10^2

t3.3 *situation 1 (the original situation in Belgium).
t3.4 **For the particular situation less than 1% of the population is higher than the microbiological limit.

t4.1 Table 4a
t4.2 Exposure (cfu per 100 g serving) to *Campylobacter* when the CMP is cooked and 10^6 iterations are conducted

t4.3 Situation	1	2	3	4	5	6	7	8	9	10
t4.4 100% percentile	1.63E+ 13	1.35E+ 11	1.12E+ 09	9.35E+ 06	7.77E+ 04	6.46E+ 02	8.67E+ 00	1.63E+ 12	1.36E+ 10	1.13E+ 08
t4.5 Mean	2.02E+ 07	1.83E+ 05	1.77E+ 03	1.98E+ 01	3.26E− 01	1.23E− 02	1.63E− 03	2.02E+ 06	1.84E+ 04	1.78E+ 02
t4.6 95% percentile	7.75E− 01	2.63E− 01	9.47E− 02	3.70E− 02	1.62E− 02	8.11E− 03	4.93E− 03	7.77E− 02	2.63E− 02	9.49E− 03

person, will develop illness, a beta distribution was used to assess the probability of illness given infection. The probability of illness was then calculated based on the probability of infection and the probability of illness given infection.

2.3.4.2. Module 4b: approach 2. The beta-poisson model used in the first approach, estimates the average risk to a population following the ingestion of an average dose. In order to estimate the probability of infection for an individual consuming a meal with a specific dose, the beta-poisson model needs to be expressed in another format. The dose–response model used in approach 2 (Table 1) reflects the same assumptions as the original beta-poisson model. However, variability for the probability of infection from a particular dose is incorporated within the simulations, so that the model estimates the risk of infection for an individual consuming a specific dose (FAO/WHO, 2002).

To calculate the probability of infection and illness, the same approach was used as in module 4a.

2.3.4.3. Module 4c: approach 3. A third approach was used, since the dose–response models that are used in the first two approaches are based on limited data. In this approach, (which was described by Oscar, 2004), an estimation of the infective dose was used. Secondly, the ratio of the ingested dose and the infective dose was calculated. When this ratio is higher than or equal to 1, infection will occur. The probability of illness given infection was again determined using the beta distribution (approach 1). The occurrence of illness given infection was represented by a binomial distribution in order to determine whether illness will occur or not.

2.4. Influence of the Campylobacter contamination level in raw chicken meat preparations on the probability of infection and illness

Since, this study was conducted in order to set a microbiological limit for *Campylobacter* spp. in poultry based meat preparations, the relative influence of lowering the contamination levels on the exposure and probability of infection and illness was estimated. For this, it was assumed that less than 1% of the CMP population has a contamination level above the microbiological limit. In order to simulate the effect of the different microbiological limits, different situations were tested by changing the parameters of the distribution (μ and σ) that describes the natural logarithm of the concentration of *Campylobacter* spp. in raw chicken meat preparations (RiskNormal (μ:σ)). These parameters were chosen in a way that the distribution represents a microbiological limit, which means that less than 1% of the population can exceed the microbiological limit. Table 2 shows the parameters of the normal distributions that were tested. Situation 1 is the original situation and this distribution was determined by fitting the normal distribution to the original data mentioned in Fig. 1. In order to test the effect of lowering the contamination level (which might be promoted e.g. by means of issuing a microbiological limit by the federal government), this distribution was adapted by reducing the standard deviation of this distribution (situation 2 to 7) and by lowering the mean of the distribution with 1 log unit (situation 8) and consequently reducing the standard deviation again (situation 9 and 10). Table 3 gives the percentage of the population of CMP that exceeds different *Campylobacter* contamination levels (from 10^{-8} until 10^6 cfu/g) and this is shown for every tested situation. For example in situation 2, 2.19% of the CMP has a *Campylobacter* concentration higher than 10^3 cfu/g, while for 10^4 cfu/g this is only 0.91%. As a consequence, situation 2 corresponds with a microbiological limit of 10^4 cfu/g, since less than 1% exceeds the contamination level of 10^4 cfu/g. The dotted line in Table 3 shows when the percentage of CMP exceeding a certain contamination level becomes lower than 1, which corresponds with the action level. Table 3 also includes, for every tested situation, the corresponding microbiological limit.

2.5. Simulation settings and modifications

In order to quantitatively estimate the expected increase in risk to the consumer when these type of food products (raw poultry based meat preparations) are consumed without prior heat treatment, the model was also run with the removal of module 2a and 2b from the model. On this occasion the number of *Campylobacter* cells that are ingested at consumption is equal to the number of *Campylobacter* cells in a raw chicken

t5.1 Table 4b
t5.2 Exposure (cfu per 100 g serving) to *Campylobacter* when the CMP is eaten raw and 10^6 iterations are conducted

t5.3 Situation	1	2	3	4	5	6	7	8	9	10
t5.4 100% percentile	1.30E+ 16	8.03E+ 13	4.94E+ 11	3.04E+ 09	1.87E+ 07	1.15E+ 05	1.18E+ 03	1.31E+ 15	8.05E+ 12	4.96E+ 10
t5.5 Mean	1.45E+ 10	9.83E+ 07	7.41E+ 05	7.22E+ 03	1.23E+ 02	5.12E+ 00	6.92E− 01	1.46E+ 09	9.86E+ 06	7.43E+ 04
t5.6 95% percentile	4.35E+ 04	8.40E+ 03	1.62E+ 03	3.13E+ 02	6.04E+ 01	1.17E+ 01	2.66E+ 00	4.36E+ 03	8.42E+ 02	1.63E+ 02

t6.1 Table 5
t6.2 Overview of the results (exposure, probability of infection, % infected) for the different tested situations

t6.3 Situation	Exposure (cfu per 100 g serving)			Approach 2 (probability of infection)			Approach 3 (% infected)
t6.4	Mean	95% percentile	100% percentile	Mean	95% percentile	100% percentile	
t6.5 1[a]	2.02E+ 07	7.75E− 01	1.63E+ 13	2.38E− 03	7.55E− 05	3.66E− 01	0.0353
t6.6 1[a] (raw)	1.45E+ 10 (sit 1×718)[b]	4.35E+ 04 (sit 1×56180)	1.30E+ 16 (sit 1×802)	4.98E− 02 (sit 1×21)	4.14E− 01 (sit 1×548)		1.0155 (sit 1×29)
t6.7 2	1.83E+ 05 (sit 1:110)	2.63E− 01 (sit 1:3)	1.35E+ 11 (sit 1:120)	1.38E− 03 (sit 1:2)	2.74E− 05 (sit 1:3)	3.55E− 01 (sit 1:1)	0.0089 (sit 1:4)
t6.8 3	1.77E+ 03 (sit 1:11390)	9.47E− 02 (sit 1:8)	1.12E+ 09 (sit 1:14469)	6.72E− 04 (sit 1:4)	1.07E− 05 (sit 1:7)	3.38E− 01 (sit 1:1)	0.0016 (sit 1:22)
t6.9 4	1.98E+ 01 (sit $1:1.0\times10^{6}$)	3.70E− 02 (sit 1:21)	9.35E+ 06 (sit $1:1.7\times10^{6}$)	2.42E− 04 (sit 1:10)	4.42E− 06 (sit 1:17)	3.16E− 01 (sit 1:1)	0.0003 (sit 1 : 118)
t6.10 5	3.26E− 01 (sit $1:6.2\times10^{7}$)	1.62E− 02 (sit 1:48)	7.77E+ 04 (sit $1:2.1\times10^{8}$)	5.50E− 05 (sit 1:43)	2.00E− 06 (sit 1:38)	2.87E− 01 (sit 1:1)	0
t6.11 6	1.23E− 02 (sit $1:1.6\times10^{9}$)	8.11E− 03 (sit 1:95)	6.46E+ 02 (sit $1:2.5\times10^{10}$)	6.33E− 06 (sit 1:376)	9.76E− 07 (sit 1:77)	1.78E− 01 (sit 1:2)	0
t6.12 7	1.63E− 03 (sit $1:1.2\times10^{10}$)	4.93E− 03 (sit 1:157)	8.67E+ 00 (sit $1:1.9\times10^{12}$)	6.75E− 07 (sit 1:3525)	5.11E− 07 sit 1:148)	6.91E− 03 (sit 1:53)	0
t6.13 8	2.02E+ 06 (sit 1:10)	7.77E− 02 (sit 1:10)	1.63E+ 12 (sit 1:10)	9.32E− 04 (sit 1:3)	5.62E− 06 (sit 1:13)	2.73E− 01 (sit 1:1)	0.0143 (sit 1:2)
t6.14 9	1.84E+ 04 (sit 1:1098)	2.63E− 02 (sit 1:29)	1.36E+ 10 (sit 1:1200)	4.44E− 04 (sit 1:5)	1.92E− 06 (sit 1:39)	2.48E− 01 (sit 1:1)	0.0024 (sit 1:15)
t6.15 10	1.78E+ 02 (sit 1:113603)	9.49E− 03 (sit 1:82)	1.13E+ 08 (sit 1:144312)	1.60E− 04 (sit 1:15)	6.88E− 07 (sit 1:110)	2.18E− 01 (sit 1:2)	0.0004 (sit 1:88)

t6.16 (raw) Indicates raw consumption of the product (no effect of cross-contamination or cooking included in the model).
[a] Situation 1 is the original situation in Belgium with regard to the distribution of the *Campylobacter* contamination level (19.68%>1 cfu/g; 12.44%>10 cfu/g; t6.17 7.28>100 cfu/g; 5%>1000 cfu/g).
t6.18 [b] (sit 1×718) indicates that the exposure is 718 times higher for sit 1 (raw) than for sit 1.

meat preparation of 100 g ($N_{rcmp}=N_{cons}$). To assess the effect of the number of iterations on the simulated exposure and probability of infection, 10^4 iterations were conducted instead of the standard 10^6 iterations in the protocol. Both for raw consumption of the food product and the reduced number of iterations, the effect on the outcome of the model for the different situations mentioned in Tables 2 and 3 was explored.

To run the simulations, Latin Hypercube sampling was used and the random generator seed was fixed at 1. This fixed value was used since, providing the model is not changed, the same simulation results can be exactly repeated. More importantly, one or more distributions can be changed within the model and a second simulation can be run to look if these changes have an effect on the model's output. It is then certain that any observed change in the result is due to changes in the model and not a result of the randomness of the sampling (Vose, 2000). In a standard protocol 10^6 iterations were carried out.

3. Results

To determine the effect of lowering the amount of *Campylobacter* spp. present in raw CMP, different situations were simulated. Situation 1 is the original situation in Belgium (Fig. 1). In order to analyse the influence of reducing the high levels of *Campylobacter* spp. without affecting the mean concentration, situations 2 to 7 (Tables 2 and 3) were simulated. For these situations the mean of the distribution that represents the natural logarithm of the *Campylobacter* concentration in raw CMP (C_{rcmp}) was the same as for situation 1, but the standard deviation was lower. Another possibility is to reduce the mean contamination level. As a consequence, the complete distribution is shifted to lower concentrations, which demands higher efforts from the CMP industry. Therefore, situation 8 was simulated with a lower mean and the same standard deviation as situation 1. To determine the combined effect of lowering the standard deviation and the mean value of the C_{rcmp}, situations 9 and 10 were included in the study. The mean C_{rcmp} was the same as for situation 8, but the standard deviation was lower.

Simulation of the exposure showed that for the maximum exposure (100% percentile) the effect of reducing the standard deviation is bigger than lowering the mean value, since situation 2 has a maximum exposure that is 120 times smaller than situation 1, while for situation 8 this is only 10 times (Table 4a). The same effect was observed for the mean and to a lesser extent for the 95% percentile. For the 50% percentile (data not shown) the effect of the reduction of the standard deviation (situation 1 to 7) is limited in comparison to the reduction of the mean (situation 1 against situation 8). This can be explained by the fact that the reduction of the mean influences all values, while the reduction of the standard deviation only influences the high values and the influence on the 50% percentile is consequently rather small. When the effect of reducing the standard deviation for the maximum and mean exposure is compared to the 95% percentile, it can be observed that the effect is higher for the maximum and mean (Table 4a). This can be explained, since the narrowing of the distribution for C_{rcmp}, reduces the occurrence of the high *Campylobacter* contamination levels and consequently reduces the highest exposures. Since the skewness of the simulated distribution of the exposure to *Campylobacter* spp. in CMP is high (e.g. +965 for situation 1), the effect of the

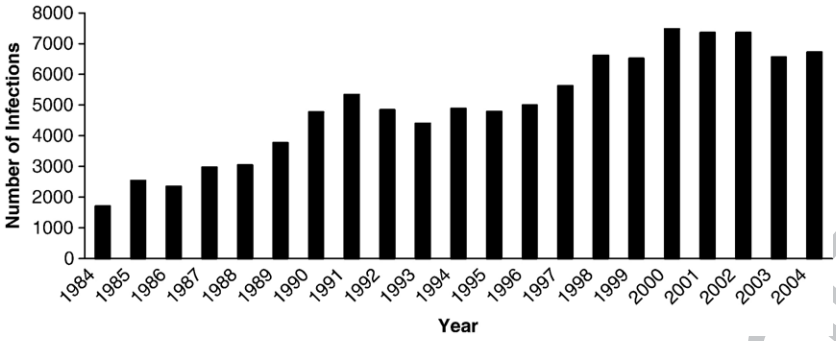


Fig. 4. Campylobacteriosis cases in Belgium (data from the Department of Epidemiology, National Institute for Public Health (ISP), Brussels, Belgium collecting data obtained from a network of sentinel and reference laboratories and from reported foodborne outbreaks).

high exposures on the mean is also big. A distribution with a positive skewness (also called right skewed) has a longer tail to the right. The higher the skewness, the longer the tail to the right and the bigger the effect of the high exposures on the mean. As a result, the effect of narrowing the distribution for C_{rcmp} is higher for the maximum (the maximum exposure in situation 1 is 10^{12} times higher than in situation 7) and the mean exposure (the mean exposure in situation 1 is 10^{10} times higher than in situation 7), than for the 95% percentile (the exposure for the 95% percentile in situation 1 is 10^{2} times higher than in situation 7). Therefore, reducing the standard deviation of the natural logarithm of the concentration of *Campylobacter* in raw CMP can contribute to a better food safety policy, because the highest exposures cause a problem for food safety.

When the chicken based meat preparation is eaten raw the maximum and mean exposure is about 100 times higher than for the heated product (Table 4b). However, the influence of eating products raw is the highest for the 50% (data not shown) and 95% percentile (Table 4b). This may be a consequence of the fact that the high intakes (which are represented by the maximum) occur when consumers mishandle and undercook food. For these consumers, the effect will be rather limited when raw products are consumed. However, the effect will be larger when consumers that follow the rules for good food hygiene (which are represented by the 50% and 95% percentile), eat the product raw.

Simulation of only 10^{4} iterations resulted in a lower maximum (3.08E+ 09 for situation 1)and mean exposure (4.00E+ 05 for situation 1) in comparison to 10^{6} iterations (Table 4a). However, for the 50 and 95% percentile this effect is much smaller. When less iterations are carried out, the chance to pick a high value is lower, which results in lower maximum and mean exposures.

Besides the exposure other outputs were also simulated. The probability of infection and illness was simulated in 3 different ways as explained in Materials and methods. The results of approach 1 are not shown, since these results are comparable to approach 2.

The maximum probability of infection is below 1 for the second approach (Table 5). As a consequence, nobody in the population is 100% certain that he or she will be infected. For situation 1 the maximum probability of infection is 0.36, which means that the person in the population with the highest risk to become infected with *Campylobacter* spp. has a chance of 36% to become infected. However, the 95% percentile for situation 1 is lower than 10^{-4}, which means that 95% of the population has a probability of infection of 7.55E− 5 or lower. The mean probability of infection was simulated to be 2.38E− 3 for situation 1, which means that, on average, 2 infections will occur for every 1000 consumptions. It is also shown that for the maximum probability of infection the effect of reducing the mean is higher than for narrowing the distribution, although the effect is rather limited. The same influence was observed for the mean and the 95% percentile. These observations were also made for the probability of illness (data not shown). The mean probability of illness was simulated to be 7.84E− 4 for situation 1 indicating that ca. 30% of infected persons will develop symptoms.

In approach 1 and 2 a dose–response model was used to estimate the probability of infection and illness. Refering to Eqs. (2) and (3) it is clear that this probability can maximally reach 1. In the third approach no dose–response model was used but the ratio of the ingested dose and the infective dose was simulated. In the present approach, infection will occur when this ratio is higher than or equal to 1. Simulation showed that the maximum ratio was higher than 1 for situation 1, 2, 3, 4, 8, 9 and 10 and Table 5 shows the percentage infected for every situation tested. It was also noted that the reduction of the standard deviation (which corresponds with the narrowing of the distribution for C_{rcmp}) has a bigger influence on the percentage infected than the reduction of the mean. For example, a reduction of the standard deviation to situation 2 resulted in 0.0089% of the population that is infected, while a reduction of the mean to situation 8 resulted in 0.0143%.

Simulation of the ratio of the ingested dose and the infective dose, when illness will occur showed that the maximum ratio was higher than 1 for situation 1, 2, 3, 8, 9 and 10. In other words people will get ill from consuming CMP, when it is contaminated in accordance to situation 1, 2, 3, 8, 9 and 10. For this approach it was again observed that reduction of the standard deviation (which corresponds with the narrowing of the distribution) has a bigger influence than reduction of the mean. For example the reduction of the standard deviation to situation 2 resulted in 0.0019% of the population that is infected, while a reduction of the mean to situation 8 resulted in 0.0048%.

4. Discussion

This study presents the results of a preliminary exposure assessment on *Campylobacter* spp. in poultry based meat preparations combined with various approaches of dose–response modelling in order to analyse the relative impact in reducing the risk for campylobacteriosis associated with a decrease in the *Campylobacter* contamination level in these types of food products. The output of various situations with different distributions of *Campylobacter* concentrations, all relating to the present situation derived from semi-quantitative data from the Belgian national *Campylobacter* surveillance program, was evaluated. It was not the objective to determine the exposure and probability of illness of the Belgian population in absolute numbers.

The annual numbers of *Campylobacter*-infections reported to the Public Health Institute (PHI), collecting human data obtained from a network of sentinel and reference laboratories and from reported foodborne outbreaks in Belgium, are shown in Fig. 4. In the period 2000–2002 a mean of 7394 human strains were isolated annually in Belgium (=72 per 100 000 inhabitants). Although a decrease in the number of reported infections seemed to have started in 2003 (63 per 100 000 inhabitants), it is too early to speak about a trend. Only one large outbreak of campylobacteriosis with 40 people affected was reported in Belgium in 2003 (Ducoffre, 2004). However, it is not established that poultry based meat preparations have indeed been implicated in foodborne campylobacteriosis in Belgium. From a questionnaire on consumption habits taken from 3000 Belgian consumers in 2004–2005, the consumption of CMP was estimated as 0.9 kg/year/inhabitant (ca. 5.5% of the total volume of meat preparations). Taking the risk estimate (mean probability of illness) in the current situation 1 being 784×10^{-04} risk/portion of 100 g consumed, the following calculation can be made 784×10^{-04} risk/portion × 0.9 kg/year/inhabitant × 10 portions/kg × 10^{7} inhabitants in Belgium = 70 560 illness per year in Belgium. From a population-based survey in the Netherlands, the prevalence of gastroenteritis was estimated as 45 per 100 persons per year whereas ca. 4.5% due to *Campylobacter*. This relates to ca. 300 000 cases of campylobacteriosis per year (population of 15.2 million in the Netherlands) (Borgdorff and Motarjemi, 1997). If applying this to the Belgian situation with a population of ca. 10 million, ca. 200 000 cases of campylobacteriosis would be expected in Belgium. Although poultry meat is considered to be the source of most human infection with *Campylobacter* outbreaks have also occurred from raw or improperly pasteurised cow's milk and from sewage polluted water (Corry and Atabay, 2001). In the present study as mentioned in the scope only poultry based meat preparations were considered (and not poultry carcasses or poultry cuts). The magnitude of the outcome of the QRA estimated as ca. 70 500 cases of campylobacteriosis in Belgium due to the type of product under consideration (CMP) seems reasonable in relation to the total number of cases estimated as 200 000. It indicates that CMP may indeed contribute to the high number of cases of campylobacteriosis. However, to confirm this risk estimate more epidemiological data are needed.

This present QRA may serve as one of the supportive factors to help risk managers to define a microbiological limit (at an "appropriate level"), which is acceptable by both the poultry processing industry and defendable by the public health authorities to control the presence of *Campylobacter* spp. in poultry based meat preparations. Although due to the lack of extended supporting data the uncertainty of the outcome may be high. A first limitation was the limitation in data to be used as an input to the model. The model is based on data that were available in Belgium and in scientific literature, however the data on the local situation in Belgium and on this particular product were rather scarce. Data on the concentration of *Campylobacter* spp. in raw CMP had a semi-quantitative nature, since only presence/absence testing in two sampling sizes were performed. As a consequence, only 3 data points were available to fit the normal distribution. Although, it might be more labour-intensive, it is important in the frame of risk assessment to collect more quantitative data (enumerations) or semi-quantitative data (presence/absence testing of a 10-fold serial dilution) in surveillance programs carried out by the competent authorities or when necessary to elaborate specific research programs to obtain a (semi-)quantitative estimate of the distribution of *Campylobacter* in the product under consideration. Also data related to consumer habits concerning food handling procedures are lacking for the Belgian situation, leading to a large degree of uncertainty. Moreover, surrogate data (e.g. prevalence of undercooking, prevalence of cross-contamination), assumptions (e.g. number of cells in outside layer) and simplifications (e.g. effect of packaging material and exact survival of *Campylobacter* during storage) had to be used, when data were not available. These and other gaps in available data for establishment of the hazard characterisation and exposure assessment are also indicated at the international level by an opinion of the EFSA Scientific Panel on Biological Hazards on *Campylobacter* in foodstuffs recently published (EFSA, 2004). This lack of data to establish a risk assessment for other hazards in other foods has also been reported by different other authors (Notermans and Batt, 1998; Anderson et al., 2001; Hartnett et al., 2001; Bemrah et al., 2002; Duffy and Schaffner, 2002; Lindqvist et al., 2002; Oscar, 2004). It is one of the most important problems quantitative risk assessment has to deal with, since predictions of quantitative risk assessment are only as good as the data used to develop and define them (Oscar, 2004). Therefore, this study has to be considered as a preliminary approach. However, the established model is available and when more data are at our disposal the model can be used to give a better estimation of the exposure to *Campylobacter* of the Belgian population.

A second important limitation of this study was the limited and questionable data on the infective dose of *Campylobacter*. These data have been based on a single human feeding study which unfortunately provides incomplete and biased information on the dose–response relation (Teunis et al., 2005). Variations in dose–response data may occur depending upon the strain. At present, little information on virulence characteristics is known for *Campylobacter* spp., neither is there a test available to establish the virulence of an isolate. Therefore, this

study also simulated the exposure to *Campylobacter* in order to draw more firm conclusions.

Taking into account these limitations it can be concluded that it is difficult to include the full concept of quantitative risk assessment at this stage. In addition, as shown from the various approaches to develop the exposure assessment, still more research input is needed to study in a critical, objective and step-by-step manner the various parts of a quantitative risk assessment. In this way the impact of the assumptions made, the lack of accurate data, the choice of the mathematical model, etc. on the outcome of the risk assessment can be acknowledged. This critical analysis of the risk assessment concept should reveal the robustness of the methodology applied, identify the *critical control points* in the risk assessment procedure as well as support the identification of the priority in the data needed and how these inputs should preferably be gathered or structured.

However, the present study provides an example on the possibilities and limitations of risk assessment towards the increasing demand of (inter)national competent authorities to establish risk-based criteria. The limitations of the model may be accepted because the focus of the QRA study was put on the relative comparison of the exposure and/or risk to public health associated with the different levels of contamination (e.g. absence of *Campylobacter* per 25 g, per 10 g, per 1 g, per 0.1 g, per 0.01 g, etc.). As such the outcome of this exercise in QRA of *Campylobacter* in CMP comparing various situations may serve the governmental concern on consumer protection in their development of preventive measures such as a "maximum acceptable level".

Since only limited data were available on the infective dose of *Campylobacter* spp., the model was simulated for different outputs (exposure, probability of infection and probability of illness using different formats to define the dose–response). Approach 1 and 2, both derived from the same study, showed that the reduction of the mean of the distribution representing the natural logarithm of the concentration of *Campylobacter* spp. in raw CMP, is the best approach to reduce the risk of *Campylobacter* in CMP. However, for the simulated exposure and approach 3 it was observed that the reduction of the standard deviation is the most appropriate technique to lower the risk of campylobacteriosis as the highest concentrations are usually the ones determining the main number of cases. It was noted in a hypothetical example on distribution of exposures of *L. monocytogenes* by Zwietering (2005) that the highest concentration range (in the example 3% of the distribution with ca. 1000/g) gives the largest contribution (70%), albeit a low prevalence. If the contamination of this 3% could be prevented in this example, the health burden would be reduced by a factor 3.3. Since the reduction of the mean corresponds with a complete shift of the contamination level of raw CMP, demanding high efforts from the CMP industry, which are most probably at present not achievable, it is proposed to lower the standard deviation of the concentration of *Campylobacter* spp. in raw CMP. This proposal corresponds with the elimination of the products that are highly contaminated. However, it should be noted that a reduction of the standard deviation not always contributes to a decrease in human infections, since this depends on the distribution curve used. Above a certain point of the dose–response relationship all exposures will lead to a maximal infection rate. The setting of a "maximum acceptable level" by the competent national authorities at retail level may be an appropriate tool to urgently stimulate the poultry processing industry to monitor the *Campylobacter* contamination level of the products offered for purchase. Internal control procedures on the *Campylobacter* level of contamination in the processing plant could be verified by the competent national control authorities by a surveillance plan and yearly the cumulative effect on the resulting (national) distribution curve could serve as an input to quantitative risk assessment to evaluate achievement of public health goals.

In order to quantify (in a relative manner) the impact of setting a microbiological limit in order to achieve reduction of the highest contamination levels on public health, the results for the three different approaches and for four situations are summarized in Table 5. Situation 4 corresponds with a microbiological limit of 100 cfu/g, situation 5 corresponds with a microbiological limit of 10 cfu/g and situation 6 corresponds with a microbiological limit of 1 cfu/g. It is clear that there is a considerable reduction in exposure and probability of infection which is most significant for the mean (respectively 10^6 times and 10 times) and also (but to a lesser extent) for the 95% percentile (respectively 21 times and 17 times) if contamination levels are controlled at ca. 100/g. Further achievement of reduction of high contamination levels, further reduces the risk, however relative reductions increase more with a 10-fold reduction of the limit from situation 5 (10/g) to situation 6 (1/g) than they do from situation 4 (100/g) to situation 5 (10/g). The third approach needs a different type of interpretation. It shows the percentage of the population that has a 100% chance of getting infected with *Campylobacter* (although it should be stated that this percentage is an estimate of the model and is not to be taken as an absolute figure for the Belgian population). In the present situation 1, the percentage is 0.0353%, whereas this is 118 times reduced if control of *Campylobacter* is achieved at ca. 100/g. In situation 5 and 6, the percentage is zero, which can be interpreted as that nobody in the population will be infected. However, the uncertainty on this result is not taken into account. In general, the evolution of the exposure or probability of infection or % infected all show the same trend: by imposing a more stringent microbiological limit (and as such control the maximum of the distribution) the risk will be decreased.

Simulation showed that eating raw CMP can give rise to exposures that are 10^{10} times higher than when the product is heated, for the 50% percentile of the population (data not shown). However, for the 95% percentile and the mean this effect is lower (respectively 56 129 and 718 times) if raw consumption of the CMP with a distribution of contamination levels as present (situation 1) is considered (Table 5). However, in case of the elimination of higher contamination levels (e.g. situation 4, >100/g), prohibition of raw consumption also reduces the exposure but to a lesser extent (respectively 8459 and 365 times for the 95% percentile and the mean). Therefore, information campaigns are necessary to inform consumers on the effect of consuming raw minced meat or competent national authorities may prohibit the sale of CMP for raw consumption.

As shown in the results, the number of iterations during a simulation had an influence only on the high exposures and consequently on the mean and maximum exposure. Therefore, it is recommended to run the model with 10^6 iterations.

As mentioned by de Swarte and Donker (2005) in discussing the concept of FSO/ALOP in national food safety policy, the phase of recognition of the existence of a problem is the first phase in a policy process. Up to this date, policy objectives with regard to *Campylobacter* incidence in CMP were not made explicit in Belgium and are a matter of debate and opinion. With the demand of the Federal Public Service (FPS) Health, Food Chain Safety and Environment to the Belgian Health Council at the end of November 2003 to perform a preliminary risk assessment concerning *Campylobacter* in CMP, the FPS wanted to have a scientific basis at its disposal as one of the factors for the development of a risk-based microbiological criterion. The quantitative indication on the relative decrease of the risk for the various options as shown in Table 5 may support the national authorities responsible for risk management and food safety policies in their decision. Apart from the preliminary risk assessment mentioned above, other relevant factors will be included in this risk management such as whether imposing a microbiological limit at a "maximum acceptable level" is technically attainable by the current processing and production methods in the poultry processing industry, the cost-effectiveness of alternative approaches, the potential economic loss in production capacity and competition power in an (inter)national framework in case of establishment of a microbiological criterion, the relevant inspection, sampling and testing methods, etc.

The setting of a microbiological limit or a microbiological standard in CMP may only be accepted and achieved to attain the public health goals if apart from a comprehensive risk assessment (by the scientific community) and risk management (by the governmental authorities) also risk communication between all the stakeholders (in the present case: scientific community, governmental authorities, poultry slaughtering and processing industry, retail, catering establishments and consumers) has taken place. Indeed, risk analysis sets the appropriate framework to communicate in a professional and open way decisions taken by the national authorities on food safety measures and the scientific basis should lead to better understanding of the stakeholders and dedication in their efforts to meet the criterion. Follow-up is needed to evaluate whether a microbiological limit is effective in relation to consumer health protection.

5. Uncited references

Allos and Blaser, 1995
Oyarzabal, 2005
Sandberg et al., 2005

Acknowledgements

The authors also wish to thank Koen Grijspeerdt, Pierrette Melin, Chris Michiels, Marianne Sindic, and Jan Van Hoof for their valuable comments during discussion of this topic in various meetings of the Belgian Health Council. The authors also acknowledge the cooperation of the Belgian Federal Agency for the Security of the Food Chain in providing the surveillance data on *Campylobacter* spp. in poultry products.

References

Allos, B.M., Blaser, M.J., 1995. Potential role of lipopolysaccharides of *Campylobacter jejuni* in the development of Guillain–Barré syndrome. J. Endotoxin Res. 2, 237–238.

Anderson, S.A., Yeaton Woo, R.W., Crawford, L.M., 2001. Risk assessment of the impact on human health of resistant *Campylobacter jejuni* from fluoroquinolone use in beef cattle. Food Control 12, 13–25.

Anonymous, 2003. Prévalence de *Salmonella* spp., *Listeria monocytogenes* et *E. coli* 0157 dans le préparations à base de viande hachée de volaille — Résultats du programme de contrôle AFSCA 2002, p. 1.

Bemrah, N., Bergis, H., Colmin, C., Beaufort, A., Milleman, Y., Dufour, B., Benet, J.J., Cerf, O., Sanaa, M., 2002. Quantitative risk assessment of human salmonellosis from the consumption of a turkey product to collective catering establishments. Int. J. Food. Microbiol. 80, 17–30.

Black, R.E., Levine, M.M., Clements, M.L., Highes, T.P., Blaser, M.J., 1988. Experimental *Campylobacter jejuni* infection of humans. J. Infect. Dis. 157, 472–479.

Bogaardt, M.J., Mangen, M.J.J., de Wit, G.A., Nauta, M.J., Havelaar, A.H., 2004. Controlling *Campylobacter* in the chicken meat chain — towards a decision support model. RIVM report 250911005, pp. 1–56.

Borgdorff, M.W., Motarjemi, Y., 1997. Surveillance of foodborne diseases: what are the options? Rapp. Trimest. Stat. Sanit. Mond. 50, 12–23.

Cahill, S.M., 2004. Risk assessment and campylobacteriosis. In: Smulders, F.J.M., Collins, J.D. (Eds.), Risk Management strategies: monitoring and surveillance. Wageningen Academic Publishers, Wageningen, pp. 151–172.

Chan, K.F., Tran, H.L., Kanenaka, R.Y., Kathariou, S., 2003. Survival of clinical and poultry-derived isolates of *Campylobacter jejuni* at a low temperature (4 °C). Appl. Environ. Microbiol. 67, 4186–4191.

Corry, J.E.L., Atabay, H.I., 2001. Poultry as a source of *Campylobacter* and related organisms. J. Appl. Microbiol. 90, 96S–114S.

Daniels, R.W., 1998. Home food safety. Food Technol. 52, 54–56.

de Swarte, C., Donker, R.A., 2005. Towards an FSO/ALOP based food safety policy. Food Control 16, 825–830.

Duffy, S., Schaffner, D.W., 2002. Monte Carlo simulation of the risk of contamination of apples with *Escherichia coli* O157:H7. Int. J. Food Microbiol. 78, 245–255.

Ducoffre, G., 2004. *Campylobacter* in humans. "Draft Report on zoonotic agents in Belgium in 2003". Working Group on Foodborne Infections and Intoxications. Institute of Public Health, Brussels, Belgium, pp. 1–38.

EFSA, 2004. Opinion of the Scientific Panel on Biological Hazards on the request from the Commission related to *Campylobacter* in animals and foodstuffs. EFSA J. 177, 1–10.

European Council, 1992. Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications. Off. J. L62, 38–48.

European Parliament and Council, 2002. Regulation (EC) No 178/2002 of the European parliament and of the council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Off. J. L31, 1–24.

FAO/WHO Working Group on Risk Assessment of Microbiological Hazards in Foods, 2002. Preliminary Report — Hazard Identification, Hazard Characterisation and Exposure Assessment of *Campylobacter* spp. in Broiler Chickens (MRA 01/05).

Ghafir, Y., China, B., Dierick, K., De Zutter, L., Daube, G., 2005. Surveillance of the prevalence and the level of contamination with *Campylobacter* on carcasses and meat of poultry, pork and beef in Belgium. Int. J. Food Microbiol. Submitted for publication.

Hartnett, E., Kelly, L., Newell, D., Wooldridge, M., Gettinby, G., 2001. A quantitative risk assessment for the occurrence of *Campylobacter* in chickens at the point of slaughter. Epidemiol. Infect. 127, 195–206.

ICMSF, 1996. *Campylobacter*. Micro-organisms in Foods 5 — Microbiological Specifications of food pathogens, pp. 45–65.

Kapperud, G., Skjerve, E., Vik, L., Hauge, K., Lysaker, A., Aalmen, I., Ostroff, S.M., Potter, M., 1993. Epidemiological investigation of risk factors for *Campylobacter* colonization in Norwegian broiler flocks. Epidemiol. Infect. 111, 245–255.

Lindqvist, R., Sylvén, S., Vågsholm, I., 2002. Quantitative microbial risk assessment exemplified by *Staphylococcus aureus* in unripened cheese made from raw milk. Int. J. Food Microbiol. 78, 155–170.

Medema, G.J., Teunis, P.F.M., Havelaar, A.H., Haas, C.N., 1996. Assessment of the dose–response relationship of *Campylobacter jejuni*. Int. J. Food Microbiol. 30, 101–111.

National Advisory Committee on Microbiological Criteria for Foods (NACMF), 1994. *Campylobacter jejuni*/*coli*. J. Food Prot. 57, 1101–1121.

Notermans, S., Batt, C.A., 1998. A risk assessment approach for food-borne *Bacillus cereus* and its toxins. J. Appl. Microbiol. 84, 51S–61S.

Oscar, T.P., 2004. A quantitative risk assessment model for *Salmonella* and whole chickens. Int. J. Food Microbiol. 93, 231–247.

Oyarzabal, O.A., 2005. Reduction of *Campylobacter* spp. by commercial antimicrobials applied during the processing of broiler chickens: a review from the United States perspective. J. Food Prot. 68, 1752–1760.

Robinson, D.A., 1981. Infective dose of *Campylobacter jejuni* in milk. Br. Med. J. 282, 1584.

Rosenquist, H., Nielsen, N.L., Sommer, H.M., Norrung, B., Christensen, B.B., 2003. Quantitative risk assessment of human campylobacteriosis with thermophilic *Campylobacter* species in chickens. Int. J. Food Microbiol. 83, 87–103.

Sandberg, M., Hofshagen, M., Ostenvik, O., Skjerve, E., Innocent, G., 2005. Survival of *Campylobacter* on frozen broiler carcasses as a function of time. J. Food Prot. 68, 1600–1605.

Solow, B.T., Cloak, O.M., Fratamico, P.M., 2003. Effect of temperature on viability of *Campylobacter jejuni* and *Campylobacter coli* on raw chicken or pork skin. J. Food Prot. 66, 2023–2031.

Teunis, P.F.M., Havelaar, A.H., 2000. The beta poisson dose–response model is not a single-hit model. Risk Anal. 20, 513–520.

Teunis, P., Van den Brandhof, W., Nauta, M., Wagenaar, J., Van Den Kerkhof, H., Van Pelt, W., 2005. A reconsideration of the *Campylobacter* dose–response relation. Epidemiol. Infect. 133, 583–592.

Vose, D., 2000. Risk analysis. A quantitative guide. John Wiley and Sons LTD, New York. (418 pp.).

Williamson, D.M., Gravani, R.B., Lawless, H.T., 1992. Correlating food safety knowledge with home food preparation practices. Food Technol. 46, 94–100.

Worsfold, D., Griffith, J., 1997. Assessment of the standard of consumer food safety behaviour. J. Food Prot. 60, 399–406.

Yoon, K.S., Burnette, C.N., Oscar, T.P., 2004. Development of predictive models for the survival of *Campylobacter jejuni* (ATCC 43051) on cooked chicken breast patties and in broth as a function of temperature. J. Food Prot. 67, 64–70.

Zwietering, M., 2005. Practical considerations on food safety objectives. Food Control 16, 817–823.